

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 04 NOV 2005
WIPO PCT

Applicant's or agent's file reference <b>95.85070</b>	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. <b>PCT/GB2004/003398</b>	International filing date ( <i>day/month/year</i> ) <b>04.08.2004</b>	Priority date ( <i>day/month/year</i> ) <b>04.08.2003</b>	
International Patent Classification (IPC) or national classification and IPC <b>B01J13/00, B01J13/02</b>			
Applicant <b>CAMURUS AB</b>			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input checked="" type="checkbox"/> <i>sent to the applicant and to the International Bureau</i> a total of two sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I      Basis of the opinion</p> <p><input type="checkbox"/> Box No. II      Priority</p> <p><input type="checkbox"/> Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV      Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V      Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI      Certain documents cited</p> <p><input type="checkbox"/> Box No. VII      Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII      Certain observations on the international application</p>			
Date of submission of the demand  <b>06.06.2005</b>		Date of completion of this report  <b>03.11.2005</b>	
Name and mailing address of the international preliminary examining authority:		Authorized Officer	
<div style="display: inline-block; vertical-align: middle;">                     European Patent Office - P.B. 5818 Patentlaan 2                      NL-2280 HV Rijswijk - Pays Bas                      Tel. +31 70 340 - 2040 Tx: 31 651 epo nl                      Fax: +31 70 340 - 3016                 </div>		<b>Willsher, C</b>  Telephone No. +31 70 340-2649	



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/003398

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-48 as originally filed

**Claims, Numbers**

1- 32 received on 04.07.2005 with letter of 01.07.2005

**Drawings, Sheets**

1/5-5/5 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
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PCT/GB2004/003398

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	2,4-10,13,15,17-19,21,22
	No: Claims	1,3,11,12,14,16,20
Inventive step (IS)	Yes: Claims	
	No: Claims	2,4-10,13,15,17-19,21,22
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/GB2004/003398

1. The remarks in the applicant's letter dated 01.07.05 are noted, but the IPEA considers Document D1 (US-A-5 531 925) to be very relevant.
2. Fragmentation process d) recited in D1 at column 10, line 6 to column 11, line 26 involves co-equilibration of starting material and an amphiphilic substance at an elevated temperature (37°C) - which is presumably attained through heating - followed by rapid cooling. The resultant particles must be regarded as amphiphilic, since an amphiphile substance is involved. Furthermore it is clearly indicated in D1 that bioactive agents can be present during this fragmentation - see column 18, lines 58-64, and that fragmentation is a process which results in loading of an active compound (column 8, lines 16-19). Claim 15 also indicates that a bioactive agent "is added at any stage of the preparation". Thus, the total disclosure of D1 is regarded as having made available, within the meaning of Rule 64.1(a) PCT, the subject-matter of present claims 1, 3, 11, 12, 14, 16, 20 - see also claims 17, 19 and 23 of D1.
3. Claims 1, 3, 11, 12, 14, 16 and 20 are not allowable under Article 33(2) PCT.
4. The additional subject-matter in present claims 2, 4-10, 13, 15, 17-19, 21, 22 does not appear to contribute towards increasing the level of active agent loading (cf. present description, page 7, first paragraph), since this has already been achieved through heating and cooling. No inventive step can be acknowledged for the said subject-matter.
5. Claims 2, 4-10, 13, 15, 17-19, 21, 22 are not allowable under Article 33(3) PCT.